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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,789

10/11/2005

Henri Tiedge

1181-13 PCT US

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EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

10/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/534,789

**Applicant(s)**

TIEDGE, HENRI

**Examiner**

Louis V. Wollenberger

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Status of Application***

Claims 1-19, filed 5/13/2005, are pending and subject to restriction as follows.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 7, 17-19, drawn to an isolated antisense molecule targeted to SEQ ID NO:1.

Group II, claim(s) 2, 7, 17-19, drawn to an isolated antisense molecule targeted to SEQ ID NO:2.

Group III, claim(s) 3, 7, 17-19, drawn to an isolated antisense molecule comprising SEQ ID NO:3.

Group IV, claim(s) 4, 7, 17-19, drawn to an isolated antisense molecule comprising SEQ ID NO:4.

Group V, claim(s) 5, 7, 17-19, drawn to an isolated antisense molecule comprising SEQ ID NO:5.

Group VI, claim(s) 6, 7, 17-19, drawn to an isolated antisense molecule comprising SEQ ID NO:6.

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Group VII, claim(s) 8, 9, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering a dominant negative mutant of BC200 RNA. Election of this group requires the further election of a single neurological disorder from claim 12.

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Group VIII, claim(s) 8, 9, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering a small interfering RNA. Election of this group requires the further election of a single neurological disorder from claim 12.

Group IX, claim(s) 8, 10, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule targeted to SEQ ID NO:1. Election of this group requires the further election of a single neurological disorder from claim 12.

Group X, claim(s) 8, 10, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule targeted to SEQ ID NO:2. Election of this group requires the further election of a single neurological disorder from claim 12.

Group XI, claim(s) 8, 11, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense comprising SEQ ID NO:3. Election of this group requires the further election of a single neurological disorder from claim 12.

Group XII, claim(s) 8, 11, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule comprising SEQ ID NO:4. Election of this group requires the further election of a single neurological disorder from claim 12.

Group XIII, claim(s) 8, 11, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule comprising SEQ ID NO:5. Election of this group requires the further election of a single neurological disorder from claim 12.

Group XIV, claim(s) 8, 11, 12, drawn to a method for treating a neurological disorder, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule comprising SEQ ID NO:6. Election of this group requires the further election of a single neurological disorder from claim 12.

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Group XV, claim(s) 8, 9, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering a dominant negative mutant of BC200 RNA. Election of this group requires the further election of a single cancer from claim 13.

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Group XVI, claim(s) 8, 9, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering a small interfering RNA. Election of this group requires the further election of a single cancer from claim 13.

Group XVII, claim(s) 8, 10, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule targeted to SEQ ID NO:1. Election of this group requires the further election of a single cancer from claim 13.

Group XVIII, claim(s) 8, 10, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule targeted to SEQ ID NO:2. Election of this group requires the further election of a single cancer from claim 13.

Group XIX, claim(s) 8, 11, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense comprising SEQ ID NO:3. Election of this group requires the further election of a single cancer from claim 13.

Group XX, claim(s) 8, 11, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule comprising SEQ ID NO:4. Election of this group requires the further election of a single cancer from claim 13.

Group XXI, claim(s) 8, 11, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule comprising SEQ ID NO:5. Election of this group requires the further election of a single cancer from claim 13.

Group XXII, claim(s) 8, 11, 13, drawn to a method for treating a cancer, comprising down-regulating BC200 RNA, and to a method thereof comprising administering an antisense molecule comprising SEQ ID NO:6. Election of this group requires the further election of a single cancer from claim 13.

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Group XXIII, claim(s) 14-16, drawn to a method for treating epilepsy, comprising up-regulating BC200 RNA.

The inventions listed as Groups I-XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, which features are defined in each of the descriptions in the listing set forth above.

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For example, Group I is drawn to an antisense targeted to SEQ ID NO:1, which feature is not specifically found and/or required in any of groups II-VI. Similarly, the special technical feature of Groups VII-XXII is the method of treating disorders or cancers by down regulating BC200, whereas XXII requires upregulating BC200. Whereas Group XV requires administering a dominant negative BC200 RNA, Group XVI requires a small interfering RNA. While the special technical feature of Groups VIII-XIV is a method for treating a neurological disorder comprising down regulating BC200, this feature is not shared by Groups XV-XXII, which require treating cancer by down regulating BC200. Thus, the groups lack unity of invention *a priori*. Similarly, groups drawn to products lack unity of invention with groups drawn to methods of using said products since the special technical features of said methods involves the step of using said products to treat a particular disease in a particular patient population, which steps and features are not found or required in any of groups I-VI. Furthermore, molecules antisense to BC200 RNA are shown in the prior art, and therefore, cannot, by themselves, be considered a special technical feature. For example, Tiedge et al. (US Patent 5,736,329) discloses antisense nucleic acid probes targeted to BC200 RNA such as SEQ ID NO:1. Therefore, unity of invention is lacking *a posteriori* as well.

Should Applicant elect either of Groups VII-XXII, Applicant must further elect a single type of disorder or cancer from claims 12 and 13, since the combination of materials and steps for treating each type of disease represents a special technical feature not shared or common to any other method thereof. Each method would be directed to a different disorder, and, most likely, a different patient population afflicted with the disorder.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/  
Examiner, Art Unit 1635  
October 10, 2007